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09/842,469	04/26/2001	Leonard Buckbinder	pc10873B	7996

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EXAMINER
MOORE, WILLIAM W

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 08/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Application No.	Applicant(s)
09/842,469	BUCKBINDER ET AL.
Examiner	**Art Unit**
William W. Moore	1652

Office Action Summary

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-18* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
4) ☐ Interview Summary (PTO-413) Paper No(s) _____
5) ☐ Notice of Informal Patent Application (PTO-152)

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. §121:

1. Claims 1 and 15, drawn to any one of many species of oligonucleotides comprising at least 15 contiguous nucleotides among the 3,776 nucleotides of SEQ ID NO:1, or a complement thereof, and to a method of use thereof in a method for detecting the presence of an ADAMTS-E-encoding polynucleotide in a sample, classified in, *inter alia* class 536, subclass 24.3.

2. Claims 1 and 15, drawn to any one of many species of oligonucleotides comprising at least 15 contiguous nucleotides among the 3,414 nucleotides of SEQ ID NO:7, or a complement thereof, and to a method of use thereof in a method for detecting the presence of an ADAMTS-E-encoding polynucleotide in a sample, classified in, *inter alia* class 536, subclass 24.3.

3. Claims 1, 2 and 8-10, drawn to any of a genus of polynucleotides isocoding for a 1104-amino acid human ADAMTS-E polypeptide set forth in SEQ ID NO:2 or any of its four component domains, or a complement thereof, an expression system comprising the polynucleotide, a host cell comprising said expression system, and a recombinant method of making the encoded polypeptide, classified, *inter alia*, in class 435, subclass 69.1.

4. Claims 1, 3 and 8-10, drawn to any of a genus of polynucleotides isocoding for a 533-amino acid human ADAMTS-E polypeptide set forth in SEQ ID NO:8 or any of its three component domains, or a complement thereof, an expression system comprising said polynucleotide, a host cell comprising said expression system, and a recombinant method of making the encoded polypeptide, classified, *inter alia*, in class 435, subclass 69.1.

5. Claims 1, 4 and 8-10, drawn to any of a genus of polynucleotides isocoding for a 1104-amino acid murine ADAMTS-E polypeptide set forth in SEQ ID NO:4 or any of its four component domains, or a complement thereof, an expression system comprising said polynucleotide, a host cell comprising said expression system, and a recombinant method of making the encoded polypeptide, classified, *inter alia*, in class 435, subclass 69.1.

6. Claims 5, 6 and, in part, 14, drawn to a human ADAMTS-E polypeptide having the 1104-amino acid sequence set forth in SEQ ID NO:2, or any of its four component domains, and to a method of use thereof in an assay to identify an inhibitor of the activity of an ADAMTS-E polypeptide, classified, *inter alia*, in class 435, subclass 226.

7. Claims 5, 7 and, in part, 14, drawn to a human ADAMTS-E polypeptide having the 533-amino acid sequence set forth in SEQ ID NO:8, or any of its three component domains, and to a method of use thereof in an assay to identify an inhibitor of the activity of an ADAMTS-E polypeptide, classified, *inter alia*, in class 435, subclass 226.

8. Claims 11 and 12, drawn to an antibody capable of binding an ADAMTS-E polypeptide and to a method of treatment to effect an altered activity of the polypeptide, comprising administering the antibody to a subject, classified in class 530, subclass 387.1

9. Claims 11 and 13, drawn to a stimulatory agent capable of binding an ADAMTS-E polypeptide and to a method of treatment to effect an altered activity of the polypeptide, comprising administering the stimulatory agent to a subject, classified in class 436, subclass 81.

10. Claims 11 and 12, drawn to an agent that inhibits the activity of an ADAMTS-E polypeptide and to a method of treatment to effect an altered activity of the polypeptide, comprising administering the inhibitory agent to a subject, classified in class 930, subclass 250.

11. Claims 11 and 12, drawn to an agent that is a substrate of an ADAMTS-E polypeptide and to a method of treatment to effect an altered activity of the polypeptide, comprising administering the substrate to a subject, classified in class 530, subclass 300.

12. Claim 13, drawn to a diagnostic method comprising a determination of the presence or absence of a mutation in a polynucleotide encoding an ADAMTS-E polypeptide having the amino acid sequence set forth in SEQ ID NO:2, classified in class 435, subclass 6.

13. Claim 13, drawn to a diagnostic method comprising a determination of the presence or absence of a mutation in a polynucleotide encoding an ADAMTS-E polypeptide having the amino acid sequence set forth in SEQ ID NO:8, classified in class 435, subclass 6.

14. Claim 14, drawn, in part, to an assay to identify a compound capable of stimulating the activity of an ADAMTS-E polypeptide having the amino acid sequence set forth in SEQ ID NO:2, classified in class 435, subclass 23.

15. Claim 14, drawn, in part, to an assay to identify a compound capable of stimulating the activity of an ADAMTS-E polypeptide having the amino acid sequence set forth in SEQ ID NO:8, classified in class 435, subclass 23.

16. Claim 14, drawn, in part, to an assay to identify a compound capable of binding an ADAMTS-E polypeptide having the amino acid sequence set forth in SEQ ID NO:2, classified in class 435, subclass 7.1.

17. Claim 14, drawn, in part, to an assay to identify a compound capable of binding an ADAMTS-E polypeptide having the amino acid sequence set forth in SEQ ID NO:8, classified in class 435, subclass 7.1.

18. Claim 16, drawn, in part, to an assay to identify a substrate of an ADAMTS-E polypeptide having the amino acid sequence set forth in SEQ ID NO:2, classified in class 435, subclass 7.72.

19. Claim 16, drawn, in part, to an assay to identify a substrate of an ADAMTS-E polypeptide having the amino acid sequence set forth in SEQ ID NO:8, classified in class 435, subclass 7.72.

20. Claims 16 and 18, drawn, both in part, to a pharmaceutical composition comprising a stimulator of the activity of an ADAMTS-E polypeptide having the amino acid sequence set forth in SEQ ID NO:2 combined with a pharmaceutically acceptable carrier, and to method of treating a medical condition comprising the administration of said composition to a person, classified in class 514, subclass 494.

21. Claims 16 and 18, drawn, both in part, to a pharmaceutical composition comprising a stimulator of the activity of an ADAMTS-E polypeptide having the amino

22. Claims 16 and 18, drawn, both in part, to a pharmaceutical composition comprising an inhibitor of the activity of an ADAMTS-E polypeptide having the amino

acid sequence set forth in SEQ ID NO:2 combined with a pharmaceutically acceptable carrier, and to method of treating a medical condition comprising the administration of said composition to a person, classified in class 514, subclass 773.

23. Claims 16 and 18, drawn, both in part, to a pharmaceutical composition comprising an inhibitor of the activity of an ADAMTS-E polypeptide having the amino acid sequence set forth in SEQ ID NO:8 combined with a pharmaceutically acceptable carrier, and to method of treating a medical condition comprising the administration of said composition to a person, classified in class 514, subclass 773.

24. Claims 16 and 18, drawn, both in part, to a pharmaceutical composition comprising an ADAMTS-E polypeptide having the amino acid sequence set forth in SEQ ID NO:2 combined with a pharmaceutically acceptable carrier, and to method of treating a medical condition comprising the administration of said composition to a person, classified in class 424, subclass 94.67.

25. Claims 16 and 18, drawn, both in part, to a pharmaceutical composition comprising an ADAMTS-E polypeptide having the amino acid sequence set forth in SEQ ID NO:8 combined with a pharmaceutically acceptable carrier, and to method of treating a medical condition comprising the administration of said composition to a person, classified in 424, subclass 94.67.

26. Claims 16 and 18, drawn, both in part, to a pharmaceutical composition comprising a polynucleotide encoding an ADAMTS-E polypeptide having the amino acid sequence set forth in SEQ ID NO:2 combined with a pharmaceutically acceptable carrier, and to method of treating a medical condition comprising the administration of said composition to a person, classified in class 514, subclass 44.

27. Claims 16 and 18, drawn, both in part, to a pharmaceutical composition comprising a polynucleotide encoding an ADAMTS-E polypeptide having the amino acid sequence set forth in SEQ ID NO:8 combined with a pharmaceutically acceptable carrier, and to method of treating a medical condition comprising the administration of said composition to a person, classified in class 514, subclass 44.

28. Claims 16 and 18, drawn, both in part, to a pharmaceutical composition comprising an oligonucleotide comprising at least 15 contiguous nucleotides among the 3,776 nucleotides of SEQ ID NO:1, or a complement thereof combined with a pharmaceutically acceptable carrier, and to method of treating a medical condition comprising the administration of said composition to a person, classified in class 536, subclass 24.5.

19. Claims 16 and 18, drawn, both in part, to a pharmaceutical composition comprising an oligonucleotide comprising at least 15 contiguous nucleotides among the 3,776 nucleotides of SEQ ID NO:7, or a complement thereof combined with a pharmaceutically acceptable carrier, and to method of treating a medical condition comprising the administration of said composition to a person, classified in class 536, subclass 24.5.

Inventions of Groups 3 and 4 and, respectively, Groups 1 and 2, are related as

subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combinations

as claimed do not require the particulars of the subcombinations as claimed because the various oligonucleotide regions described by clause (b) of claim 1 may be substituted with isocoding oligonucleotides not having a sequence present in either of SEQ IDs NOs:1 or 7. The subcombinations have separate utilities such as use as hybridization probes or use as primers for the polymerase chain reaction.

Inventions of Groups 1 and 2 are unrelated to inventions of Groups 5-27. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed to be capable of use together and have different modes of operation, different functions, and different effects.

Inventions of Groups 1 and 2 and, respectively, Groups 28 and 29, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the processes of using products as claimed in Groups 1 and 2 is materially different from the processes of using those products as claimed in Groups 28 and 29.

Inventions of Groups 3 and 4 and, respectively, Groups 6 and 7, are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the products of Groups 6 and 7 may be made by another and materially different process.

Inventions of Groups 3 and 4 are unrelated to inventions of Groups 5, 8-11, 14-25, 28 and 29. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed to be capable of use together and have, variously, different

Inventions of Groups 5 and 8 and, respectively, Groups 12 and 13, are related as product and process of use. The inventions can be shown to be distinct if either or both of

the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the processes of using products as claimed in Groups 3 and 4 is materially different from the processes of using those products as claimed in Groups 12 and 13.

Inventions of Groups 3 and 4 and, respectively, Groups 26 and 27, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the processes of using products as claimed in Groups 1 and 2 is materially different from the processes of using those products as claimed in Groups 26 and 27.

The invention of Group 5 is unrelated to inventions of Groups 6-29. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed to be capable of use together and have, variously, different modes of operation, different functions, and/or different effects.

Inventions of Groups 6 and 7 are unrelated to the inventions of Groups 8-13, 20-23, and 26-29. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed to be capable of use together and have, variously, different modes of operation, different functions, and/or different effects.

Inventions of Groups 6 and 7 and Groups 14-19, 24 and 25 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant

The invention of Group 8 is unrelated to inventions of Groups 9-29. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed to be capable of use together and have, variously, different modes of operation, different functions, and/or different effects.

The invention of Group 9 is unrelated to inventions of Groups 10-19 and 22-29. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed to be capable of use together and have, variously, different modes of operation, different functions, and/or different effects.

The invention of Group 9 and Groups 20 and 21 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed in Group 9 can be used in a materially different process of using that product *in vitro*.

The invention of Group 10 is unrelated to inventions of Groups 11-21 and 24-29. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed to be capable of use together and have, variously, different modes of operation, different functions, and/or different effects.

The invention of Group 10 and Groups 22 and 23 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially

[illegible] product *in vitro*.

The invention of Group 11 is unrelated to inventions of Groups 12-29. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed to be capable of use together and have, variously, different modes of operation, different functions, and/or different effects.

Inventions of Groups 12 and 13 are unrelated to the inventions of Groups 14-29. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed to be capable of use together and have, variously, different modes of operation, different functions, and/or different effects.

Inventions of Groups 14 and 15 are unrelated to the inventions of Groups 16-29. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed to be capable of use together and have, variously, different modes of operation, different functions, and/or different effects.

Inventions of Groups 16 and 17 are unrelated to the inventions of Groups 18-29. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed to be capable of use together and have, variously, different modes of operation, different functions, and/or different effects.

Inventions of Groups 18 and 19 are unrelated to the inventions of Groups 20-29. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed to be capable of use together and have, variously, different modes of

Inventions of Groups 20 and 21 are unrelated to the inventions of Groups 22-29. Inventions are unrelated if it can be shown that they are not disclosed as capable of use

together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed to be capable of use together and have, variously, different modes of operation, different functions, and/or different effects.

Inventions of Groups 22 and 23 are unrelated to the inventions of Groups 24-29. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed to be capable of use together and have, variously, different modes of operation, different functions, and/or different effects.

Inventions of Groups 24 and 25 are unrelated to the inventions of Groups 26-29. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed to be capable of use together and have, variously, different modes of operation, different functions, and/or different effects.

Inventions of Groups 26 and 27 are unrelated to the inventions of Groups 28 and 29. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed to be capable of use together and have, variously, different modes of operation, different functions, and/or different effects.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Inventions of Groups 3, 12 and 26 are unrelated to the inventions of Groups 4, 13 and 27. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups 3 and 4 and the separate additional methods of use of thereof

ADAMTS-1 polypeptides having common catalytic, functional and immunogenic features where the protease domain of a polypeptide encoded by a member of the genus of

polynucleotides isocoding with SEQ ID NO:1 differs from that of the protease domain encoded by a member of the genus of polynucleotides isocoding with SEQ ID NO:1 and where the polypeptide encoded by a member of the genus of polynucleotides isocoding with SEQ ID NO:7 lacks the thrombospondin domain of the polypeptide encoded by a member of the genus of polynucleotides isocoding with SEQ ID NO:1. Claim 1 describes polynucleotides encoding distinct domains as well as integral polypeptides thus the different inventions have different functions and effects and are not disclosed to be capable of use together.

Because these inventions are distinct for the reasons given above and the search required for Group 3 is not required for Group 4, restriction for examination purposes as indicated is proper.

Inventions of Groups 5, 14, 16, 18 and 24 are unrelated to the inventions of Groups 6, 15, 17, 18 and 25. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups 5 and 6, and the separate, additional, methods of use of thereof, respectively, inventions of Groups 14, 16, 18 and 24 and Groups 15, 17, 18 and 25, describe ADAMTS-E polypeptides that need not have common catalytic, functional and immunogenic features where the protease domain of a polypeptide having the amino acid sequence of SEQ ID NO:2 differs from that of the protease domain encoded by a member of the genus of polynucleotides isocoding with SEQ ID NO:8 and where the polypeptide having the amino acid sequence of SEQ ID NO:8 lacks the thrombospondin domain of the polypeptide having the amino acid sequence of SEQ ID NO:2. Claim 5 describes distinct domains as well as integral polypeptides and the different inventions have different functions and effects and are not disclosed to be capable of use together.

Because these inventions are distinct for the reasons given above and the search required for Group 5 is not required for Group 6, restriction for examination purposes as indicated is proper.

A telephone call was made to Mr. Seth H. Jacobs on August 6, 2002 to request an oral election to the above restriction requirement, but did not result in an election being

[illegible] CFR 1.143).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 703.308.0583. The examiner can normally be reached between 7:00AM-5:30PM EST on Mondays and Wednesdays, between 7:00AM-1:30PM EST on Tuesdays and Thursdays, and between 8:30AM and 5:00PM EST on Fridays. **The examiner's direct FAX telephone number is 703.746.3169.** If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached at 703.308.3804. Further fax phone numbers for the organization where this application or proceeding is assigned are 703.308.4242 for regular communications and 703.308.0294 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.0196.

William W. Moore
August 6, 2002